

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Francis Sullivan *et al.*

Serial No.:

Filed: herewith

For: HUMAN GDP-MANNOSE 4,6  
DEHYDRATASE

Attorney Docket No.: GFN-5285DV3CPACN

Group Art Unit:

Examiner:

Commissioner for Patents  
Washington, D.C. 20231

**CERTIFICATION UNDER 37 CFR 1.10**

Date of Deposit: June 11, 2001

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I hereby certify that this 37 CFR 1.53(d) request and the documents referred to therein as enclosed are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and addressed to the Commissioner for Patents, Washington, D.C. 20231.

Larry Taylor  
Name of Person Mailing Paper

Larry Taylor  
Signature of Person Mailing Paper

**PRELIMINARY AMENDMENT**

Dear Sir:

Prior to examination, please amend this application as follows:

**In the Claims:**

Please cancel claims 1-8 and 10-20 without prejudice.

Please add new claims 21-37 as follows:

21. (NEW) A method for treating a subject having an inflammatory disorder characterized by aberrant GM4,6D polypeptide activity or aberrant GM4,6D nucleic acid

expression comprising administering to the subject a GM4,6D modulator, thereby treating said subject having an inflammatory disorder.

22. (NEW) A method for treating a subject having a disorder characterized by aberrant cellular fucosylation comprising administering to the subject a GM4,6D modulator, thereby treating said subject having a disorder characterized by aberrant cellular fucosylation.

23. (NEW) A method for modulating an inflammatory response in a subject comprising administering to the subject a GM4,6D modulator, thereby modulating an inflammatory response in said subject.

24. (NEW) A method for modulating cellular fucosylation in a subject comprising administering to the subject a GM4,6D modulator, thereby modulating cellular fucosylation in said subject.

25. (NEW) The method of claim 22, wherein the disorder is a disorder associated with aberrant fucosylation of glycoconjugates.

26. (NEW) The method of either of claims 21 or 22, wherein the disorder is a disorder selected from the group consisting of: arthritis, transplant rejection, asthma, sepsis, reperfusion injury, stroke, infection, and leukocyte adhesion deficiency II.

27. (NEW) The method of any one of claims 21-24, wherein the GM4,6D modulator is capable of modulating GM4, 6D polypeptide activity.

28. (NEW) The method of claim 27, wherein the GM4,6D modulator is an inhibitor of GM4,6D activity.

29. (NEW) The method of claim 27, wherein the GM4,6D modulator is an anti-GM4,6D antibody.

30. (NEW) The method of claim 27, wherein the GM4,6D modulator is a GM4,6D polypeptide comprising the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3, or a fragment thereof having GM4,6D activity.

31. (NEW) The method of claim 27, wherein the GM4,6D modulator is a polypeptide encoded by a naturally occurring allelic variant of the nucleotide sequence of SEQ ID NO:1.

32. (NEW) The method of claim 27, wherein the GM4,6D modulator is a polypeptide having GM4,6D activity, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes with the nucleotide sequence of SEQ ID NO:1 in either 4X SSC at 65°C or 50% formamide and 4X SSC at 42°C.

33. (NEW) The method of any one of claims 21-24, wherein the GM4,6D modulator is capable of modulating GM4,6D nucleic acid expression.

34. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1, or a fragment thereof .

35. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule comprising a naturally occurring allelic variant of the nucleotide sequence of SEQ ID NO:1.

36. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule encoding a polypeptide having GM4,6D activity, wherein the

nucleic acid molecule hybridizes with the nucleotide sequence of SEQ ID NO:1 in either 4X SSC at 65°C or 50% formamide and 4X SSC at 42°C.

37. (NEW) The method of claim 35, wherein the GM4,6D modulator is a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3, or a fragment thereof having GM4,6D activity.

### **REMARKS**

Claims 1-8 and 10-20 have been canceled. The cancellation of these claims should in no way be construed as an acquiescence by Applicants to any of the rejections of record involving these claims.

Claims 21-37 have been newly added. Support for new claims 21-37 can be found in the specification and claims as originally filed. In particular, support for new claims 21- 28 and 33 may be found at least at page 4, lines 19-25, at page 5, lines 15-28, and at page 9, lines 8-11. Support for new claim 29 can be found at least at page 9, lines 1-7. Support for new claims 30-32 and 34-37 may be found at least at page 3, line 2 to page 4, line 11, at page 5, lines 2-5, and at page 5, line 29 to page 6, line 2.

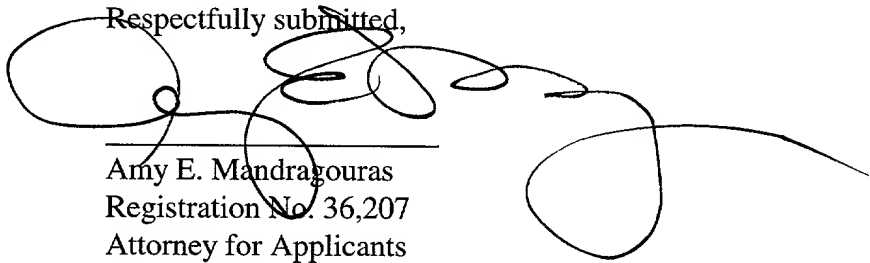
Applicants submit herewith a **“Version with Markings to Show Changes Made,”** which indicates the specific amendments made to the specification and the claims. No new matter has been added.

Any amendments to and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

**CONCLUSION**

It is respectfully submitted that this application is in condition for allowance. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Respectfully submitted,



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Dated: June 11, 2001

**Version with Markings to Show Changes Made**

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New claims 21-37 have been added as follows:

21. (NEW) A method for treating a subject having an inflammatory disorder characterized by aberrant GM4,6D polypeptide activity or aberrant GM4,6D nucleic acid expression comprising administering to the subject a GM4,6D modulator, thereby treating said subject having an inflammatory disorder.

22. (NEW) A method for treating a subject having a disorder characterized by aberrant cellular fucosylation comprising administering to the subject a GM4,6D modulator, thereby treating said subject having a disorder characterized by aberrant cellular fucosylation.

23. (NEW) A method for modulating an inflammatory response in a subject comprising administering to the subject a GM4,6D modulator, thereby modulating an inflammatory response in said subject.

24. (NEW) A method for modulating cellular fucosylation in a subject comprising administering to the subject a GM4,6D modulator, thereby modulating cellular fucosylation in said subject.

25. (NEW) The method of claim 22, wherein the disorder is a disorder associated with aberrant fucosylation of glycoconjugates.

26. (NEW) The method of either of claims 21 or 22, wherein the disorder is a disorder selected from the group consisting of: arthritis, transplant rejection, asthma, sepsis, reperfusion injury, stroke, infection, and leukocyte adhesion deficiency II.

27. (NEW) The method of any one of claims 21-24, wherein the GM4,6D modulator is capable of modulating GM4, 6D polypeptide activity.

28. (NEW) The method of claim 27, wherein the GM4,6D modulator is an inhibitor of GM4,6D activity.

29. (NEW) The method of claim 27, wherein the GM4,6D modulator is an anti-GM4,6D antibody.

30. (NEW) The method of claim 27, wherein the GM4,6D modulator is a GM4,6D polypeptide comprising the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3, or a fragment thereof having GM4,6D activity.

31. (NEW) The method of claim 27, wherein the GM4,6D modulator is a polypeptide encoded by a naturally occurring allelic variant of the nucleotide sequence of SEQ ID NO:1.

32. (NEW) The method of claim 27, wherein the GM4,6D modulator is a polypeptide having GM4,6D activity, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes with the nucleotide sequence of SEQ ID NO:1 in either 4X SSC at 65°C or 50% formamide and 4X SSC at 42°C.

33. (NEW) The method of any one of claims 21-24, wherein the GM4,6D modulator is capable of modulating GM4,6D nucleic acid expression.

34. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:1, or a fragment thereof .

35. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule comprising a naturally occurring allelic variant of the nucleotide sequence of SEQ ID NO:1.

36. (NEW) The method of claim 33, wherein the GM4,6D modulator is a nucleic acid molecule encoding a polypeptide having GM4,6D activity, wherein the nucleic acid molecule hybridizes with the nucleotide sequence of SEQ ID NO:1 in either 4X SSC at 65°C or 50% formamide and 4X SSC at 42°C.

37. (NEW) The method of claim 35, wherein the GM4,6D modulator is a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:3, or a fragment thereof having GM4,6D activity.